We claim:

1. An apparatus for inducing phase separation in a pharmaceutical grade cell lysate comprising:

a conduit comprising a cell lysate solution in fluid communication with a gas port through which a gas is forced under pressure into the conduit comprising the cell lysate solution thereby controllably forming bubbles in the cell lysate solution.

2. The apparatus of claim 1, wherein the cell lysate solution is a bacterial cell lysate solution.

3. The apparatus of claim 2, wherein the bacterial cell lysate solution comprises an alkaline lysis buffer and the bubbles effect flotation and separation of a cell debris phase from a clarified lysate phase following addition of a precipitation buffer solution.

4. The apparatus of claim 1, wherein the gas port comprises an aperture comprising a plurality of pores.

5. The apparatus of claim 4, wherein the pores have an average diameter of less than approximately 5 microns.

6. The apparatus of claim 5, wherein the aperture comprising a plurality of pores is a sparge stone or disk filter comprising pores having an approximate average diameter of 2 microns or less.

7. An apparatus for pharmaceutical grade bacterial cell lysis comprising a fluid flow path comprising and in fluid communication with:

a cell lysis buffer conduit;

a cell suspension conduit;

a precipitation buffer conduit; and

a gas introduction port comprising a plurality of pores for controllably introducing a stream of bubbles into the fluid flow path.

8. The apparatus of claim 7, wherein the fluid flow path comprises one or more static mixers.

9. The apparatus of claim 7, wherein the pores of the gas introduction port have an average diameter of less than approximately 5 microns.

10. The apparatus of claim 7, further comprising a pH adjustment buffer conduit.

11. The apparatus of claim 7, further comprising a lysate separation tank.

12. The apparatus of claim 7 wherein the fluid flow path is a contained continuous flow fluid path.

13. A continuous flow pharmaceutical grade apparatus for lysing bacterial cells comprising a fluid flow path comprising and in fluid communication with:
a conduit for introduction of a cell lysis buffer into the fluid flow path;
a sparge stone disposed in the fluid path for introducing a controlled flow of gas into the fluid path;
a conduit for introducing a bacterial cell suspension into the fluid flow path;
a first in-line mixer for combining the bacterial cell suspension and the lysis buffer thereby forming a cell lysate;
a conduit for introducing a precipitation buffer into the cell lysate;
a second in-line mixer for combining the cell lysate with the precipitation buffer thereby forming a precipitated lysate; and
a lysate tank for receiving the precipitated lysate and permitting the flotation and separation of a precipitate phase from a clarified lysate phase.

14. The apparatus of claim 13, wherein the cell lysis buffer is a alkaline lysis buffer and the precipitation buffer comprises potassium acetate.

15. The apparatus of claim 14, further comprising a conduit for introducing a pH adjustment buffer into the precipitated lysate and a third in-line mixer for combining the pH adjustment buffer and the precipitated lysate prior to flowing into the lysate tank.

16. A process of clarifying a bacterial lysate comprising plasmid DNA and cellular debris, comprising the steps of:

(a) introducing a gas into a fluid stream comprising a suspended bacterial cell suspension and a lysis buffer under conditions forming an entrainment of bubbles in the fluid stream;

(b) admixing a precipitation buffer into the fluid stream, wherein the entrained bubbles generate a buoyant precipitate comprising the cellular debris;

(c) allowing the buoyant precipitate to coalesce and separate over a fluid phase comprising the plasmid DNA; and

(d) collecting the fluid phase comprising the plasmid DNA.

17. The process of claim 16, wherein the lysis buffer is an alkaline lysis buffer.

18. The process of claim 16, wherein the gas is introduced through an aperture comprising a plurality of pores of less than approximately 5 microns in diameter.

19. The process of claim 18, wherein the pores are approximately 2 microns in diameter.

20. A cell lysis process wherein cells in suspension are lysed in the presence of a controlled stream of gas bubbles sufficient to cause flotation and separation of a cellular debris component over a clarified lysate component comprising extrachromosomal nucleic acids.

21. The process of claim 20 wherein the lysis process is an in-line process for alkaline lysis of bacterial cells and results in flotation of a cellular debris component following addition of a precipitation buffer.

22. A method for the purification of extrachromosomal DNA from a pharmaceutical grade bacterial fermentation, comprising the steps of:

(a) generating a fluidized stream of bacterial cells;

(b) introducing a lysis buffer and a gas into the fluidized stream to form a cell lysate solution comprising a plurality of bubbles;

(c) introducing a precipitation solution into the cell lysate solution wherein combined action of the bubbles and the precipitation solution results in the formation of a buoyant precipitate comprising cell debris and chromosomal DNA;

(d) allowing the buoyant precipitate to coalesce and separate from an underlying fluid phase comprising the extrachromosomal DNA;

(e) collecting underlying fluid phase to form a clarified lysate;

(f) filtering the clarified lysate; and

(g) subjecting the filtered clarified lysate to ion exchange chromatography to separate the extrachromosomal DNA from residual contaminants.

23. A method of producing a clarified cell lysate comprising plasmid DNA from an alkaline bacterial cell lysate, comprising the steps of:

introducing a suspension of bacterial cells into a fluid flow comprising an alkaline lysis buffer and an entrainment of gas, wherein the cells are flowably mixed with the cell lysis buffer together with the gas thereby forming a cell lysis mixture;

introducing a precipitation buffer into the fluid flow comprising the cell lysis mixture, thereby forming a cell debris precipitate in the cell lysis mixture;

separating the mixture into a buoyant flocculent phase comprising the precipitated cell debris and a fluid phase comprising a substantially clarified cell lysate; and

isolating the substantially clarified cell lysate.